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VICH GLs: data to be provided to apply for waiving of TABST (and LABST in future)

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Background to VICH

- VICH = *The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products*
- 1996: animal health industry and regulators from the European Union, Japan and the United States with Australia/New Zealand and Canada joining as observers.

➢ Harmonise regulatory requirements in the VICH regions to ensure high quality, safety and efficacy standards, even as it reduces the number of animals needed for testing and the associated costs;

➢ Provide a basis for wider international harmonisation of registration requirements;

➢ For more information: http://www.vichsec.org/

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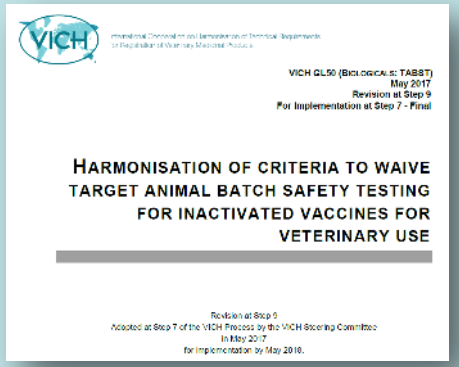
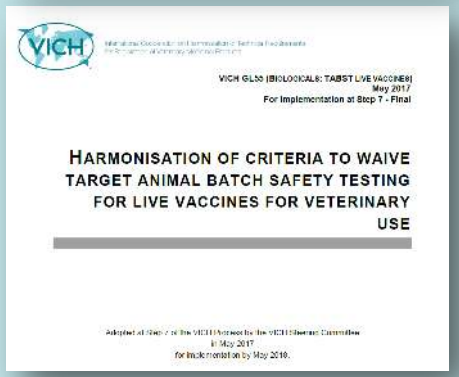
Status of VICH GL development

- EU launched discussion in 2008
- VICH decision to focus on TABST
  - GL50 (live vaccines) published in 2013 to be implemented by 2014
  - Revised GL50 and GL55 (inactivated vaccines) published in 2018 to be implemented by 2019
  - GL50 & 55 included in OIE manual 2018
- Work on LABST GL started in 2016
  - Data collection served as basis


VICH GL50 (BIOLOGICALS: TABST)
May 2017
Revision at Step 9
For Implementation at Step 7 - Final

HARMONISATION OF CRITERIA TO WAIVE TARGET ANIMAL BATCH SAFETY TESTING FOR INACTIVATED VACCINES FOR VETERINARY USE


VICH GL50 (BIOLOGICALS: TABST LIVE VACCINES)
May 2017
For Implementation at Step 7 - Final

HARMONISATION OF CRITERIA TO WAIVE TARGET ANIMAL BATCH SAFETY TESTING FOR LIVE VACCINES FOR VETERINARY USE

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Criteria for waivers

Manufacturers:

- demonstrate that the product is produced following VICH principles (e.g. seed lot system, quality control & assurance, pharmacovigilance);
- present data of a suitable number of batches (e.g. 10 or less, e.g. 5, if 10 batches are not produced within 3 years);
- can use data from combined vaccines
- provide a dossier for each vaccine; and
- apply for waivers with regulatory authority.

❖ Regulatory authorities decide on waivers.

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Thank you!

Questions?

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